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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,780	BOUCHARD ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,26-34 and 36-46* is/are pending in the application.

4a) Of the above claim(s) *43-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,26-34 and 36-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. By Amendment filed 02/28/07, claims 22, 29-31, 33-34 and 36-39 have been amended and claims 43-46 have been newly added.

With respect to the claims 43-46, the newly submitted claims are directed to an invention that is independent or distinct from the invention originally claimed invention.

It is noted that applicant originally has received an action on the merits for the originally presented invention which is directed to a method of treating infertility disorders by administering an LHRH-antagonist, inducing follicle growth by hMG or FSH in combination with clomiphene, this invention has been elected by original presentation for prosecution on the merits. However, the amendment filed on 02/28/07 introduces new set of claims drawn to a non-elected invention ((i) a method of controlled ovarian stimulation (claims 43-44) and (ii) a method of treating fertility disorders by administering an LHRH antagonist, inducing follicle growth by hMG or FSH in combination with clomiphene and performing assisted reproduction technique following induction of ovulation (claims 45-46)). Accordingly, claims 43-46 are withdrawn from further consideration by the examiner as being drawn to the non-elected invention.

2. Claims 22, 26-34 and 36-42 are currently pending for prosecution on the merits of the case.

3. Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby

withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 22, 28-32, 36, 39-42 are rejected under 35 USC 102 (a) as being anticipated by Hwang et al. (Human Reproduction. Vol. 18, No. 1, pp. 45-49, 2003).

Hwang teaches the administration of LHRH antagonist such as cetrorelix and inducing follicle growth by the administration of hMG in combination with clomiphene for treatment of female infertility, wherein ovulation is induced by HCG; clomiphene is administered daily dosage of 100 mg from day 3 to 7 days; cetrorelix is administered as daily 2.5 s.c. injection started on 6^{th} day of the ovarian stimulation followed by a multiple daily dose of 0.25mg injections (abstract; "Materials and Methods" in page 46; "Discussion" pages 48-49).

Although Hwang does not mention specifically about the activity of LHRH antagonist (i.e., cetrorelix) in "suppressing endogenous LH while maintaining FSH secretion at a natural level and estrogen development is not affected until ovulation induction" (claim 22) or "luteal phase supplementation is avoided and negative effects of HCG are prevented during the luteal phase" (claim 37), such property must be inherently presented in the referenced method. The

prior art directing the administration of same compound in overlapping dosage to same patient population for the same intended purpose as disclosed by the applicant anticipates the applicant's claim even absent explicit recitation of the mechanism of action.

5. Claims 22, 26, 28 and 39-42 are rejected under 35 USC 102 (b) as being anticipated by Craft et al. (Human Reproduction. Vol. 14, No. 12, pp. 2959-2962, 1999).

Craft teaches the administration of LHRH antagonist such as cetrorelix and inducing follicle growth by the administration of human gonadotrophin in combination with clomiphene for the treatment of female infertility, wherein clomiphene is administered daily dosage of 100 mg from day 2 for 5 days; cetrorelix is administered as daily 0.25 mg s.c. injection started on the 5^{th} or 6^{th} day of gonadotrophin (abstract; "Drug Protocol" in page 2960 and "Discussion" in page 2961).

Although Craft does not mention specifically about the activity of LHRH antagonist (i.e., cetrorelix) in "suppressing endogenous LH while maintaining FSH secretion at a natural level and estrogen development is not affected until ovulation induction" (claim 22) or "after cessation of cetrorelix administration, subsequent follicle development is facilitated with remaining endogenous LH and FSH" (claim 39), such property must be inherently presented in the referenced method. The prior art directing the administration of the same compound in overlapping dosage to the same patient population for the same intended purpose as disclosed by the applicant anticipates the applicant's claim even absent explicit recitation of the mechanism of action.

6. Claims 22, 27-28, 36-37 and 39-42 are rejected under 35 USC 102 (b) as being anticipated by Engel et al. (Human Reproduction. Vol. 17, No. 8, pp. 2022-2026, 2002).

Engel teaches the administration of LHRH antagonist such as cetrorelix and inducing follicle growth by the administration of human gonadotrophin or rFSH in combination with clomiphene for treatment of female infertility, wherein ovulation is induced by HCG; clomiphene is administered daily dosage of 100 mg from day 2 or 3 to 7 days (group 1) or 2 or 3 days to 5 days (group 2); cetrorelix is administered as daily 0.25mg s.c. injection started on 6th day of the ovarian stimulation (abstract; Figure 1; "Stimulation Protocols" in page 2023; "Discussion" in pages 2024-2025).

Although Engel does not mention specifically about the activity of LHRH antagonist (i.e., cetrorelix) in "suppressing endogenous LH while maintaining FSH secretion at a natural level and estrogen development is not affected until ovulation induction" (claim 22), "luteal phase supplementation is avoided and negative effects of HCG are prevented during the luteal phase" (claim 37) or "after cessation of cetrorelix administration, subsequent follicle development is facilitated with remaining endogenous LH and FSH" (claim 39), such property must be inherently presented in the referenced method. The prior art directing the administration of the same compound in overlapping dosage to the same patient population for the same intended purpose as disclosed by the applicant anticipates the applicant's claim even absent explicit recitation of the mechanism of action.

7. Claims 22, 33-38 and 39 are rejected under 35 USC 102 (b) as being anticipated by Engel et al. (WO 99/55357).

Engel teaches the administration of LHRH antagonist such as cetrorelix and inducing follicle growth by the administration of human gonadotrophin or rFSH in combination with clomiphene for treatment of female infertility, wherein ovulation is induced by HCG, native

LHRH, LHRH-agonists or recombinant LH (abstract; page 1, lines 24-33; page 3, lines 4-26; claims).

Although Engel does not mention specifically about the activity of LHRH antagonist (i.e., cetrorelix) in "suppressing endogenous LH while maintaining FSH secretion at a natural level and estrogen development is not affected until ovulation induction" (claim 22), "luteal phase supplementation is avoided and negative effects of HCG are prevented during the luteal phase" (claim 37), "ovarian hyperstimulation syndrome is avoided" (claim 38), or "after cessation of cetrorelix administration, subsequent follicle development is facilitated with remaining endogenous LH and FSH" (claim 39), such property must be inherently presented in the referenced method. The prior art directing the administration of the same compound in overlapping dosage to the same patient population for the same intended purpose as disclosed by the applicant anticipates the applicant's claim even absent explicit recitation of the mechanism of action.

Response to Arguments

8. Applicant's arguments filed 02/28/07 have been fully considered but they are not persuasive.

In response to applicant's effort to overcome the rejection of record by perfecting priority benefit under 35 USC 119(e) or 120, the examiner recognizes that it is not within the time periods set in 37 CFR 1.78(a) or filing a grantable petition under 37 CFR 1.78(a). Thus, the examiner maintains the rejection of record.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e) or 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due

under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. No Claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
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